Remarks

In an Office Action issued January 6, 2003, which Action was made Final, the Examiner withdrew all previous rejections except for the last rejection under 35 USC § 103, which was withdrawn in favor of a new 35 USC § 103 rejection. The Examiner further set forth new grounds of rejection under 35 USC § 112. These matters are addressed separately herein.

Rejections under 35 USC § 112

Claims 42 and 45 were rejected as depending on cancelled claim 36. Claims 42 and 45 have been amended to depend on claim 33, which is currently pending. This amendment is believed to address the Examiner's rejection; accordingly, applicants request that the rejection be withdrawn.

Claims 27 and 28 were rejected for referring to amino acids of SEQ ID NO:1 when SEQ ID NO:1 is a nucleic acid sequence. Applicants respectfully note that SEQ ID NO:1 presents both nucleic acid and amino acid sequence, however, applicants have amended the claims as discussed below, and they no longer refer to SEQ ID NO:1. Accordingly, the rejection is moot, and applicants request that it be withdrawn.

Claims 27, 32, 33, 38, 40, 50-56 and 68-70 were rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of that which was claimed at the time the application was filed. According to the Examiner, the specification does not provide adequate written description of a polypeptide having at least 90% identity with amino acids 49-220 of SEQ ID NO:19 or amino acids 47-215 of SEQ ID NO:23. Applicants have amended the claims to more particularly point out and distinctly claim what they regard as their invention, by including a recitation of the ability of the polypeptides to bind CD30. This amendment does not alter the scope of the claims, but is believed to satisfy the Examiner's concern as set forth in the Office Action and discussed during the telephone interview. Support for the amendment is found throughout the specification and claims as filed, for example at pages 9 through 11 and page 12, line 29 through page 14, line 4 as well as in the Examples. Accordingly, applicants request that the rejection be withdrawn.

Rejections under 35 USC § 103

Claims 27-30, 32-33, 38-40, 42-43, 45, 50-66 and 68-70 were rejected under 35 USC § 103(a) as being unpatentable over Thorpe et al. (U.S. 5,165,923) in view of Verheul et al. (WO 92/00762), Smith et al. (*Cell* 73:1349; 1993), Goodwin et al. (WO 93/24135), and applicant's own specification, in light of Stein et al. (DE 4200043; US 5,866,372). According to the Examiner, Thorpe et al. teach a method of delivering a therapeutic agent to CD30+ cells comprising contacting said cells with a conjugate comprising toxins attached to an anti-CD30 antibody. The Examiner goes on to assert that Verheul et al. disclose the use of targeting toxin to receptors using antibodies, fragments thereof or using natural ligand receptor for the receptor. Smith et al. and Goodwin et al. are cited as allegedly teaching the nucleic acid and amino acid sequences of CD30L. The Examiner asserts that Stein et al. disclose CD30 nucleic and amino acid sequences. Applicants respectfully disagree that the cited references, alone or in combination, suggest or disclose the present invention, for the reasons set forth in the response to the previous Office Action, which response was filed October 18, 2002, and is hereby incorporated by reference, in light of the discussion set forth below.

At the outset, applicants respectfully assert that the present specification is not citable against itself as prior art. The disclosure on page 15 is intended to teach those of ordinary skill in the art how to make and use the claimed invention, and is not an admission that that invention is taught or suggested in the prior art. With respect to Thorpe et al., applicants respectfully disagree with the Examiner's assertion that Thorpe et al teach or suggest CD30 binding ligands other than CD30 antibodies. At column 4, lines 51 though 55, Thorpe et al. suggest that their invention is not limited to antibodies to the CD30 antigen, and propose that other target antigens can be suitably employed in their claimed invention, i.e. in the preparation of immunotoxin conjugates. That Thorpe et al. envision the use of antibodies to cell surface antigens as ligands is shown in column 3, lines 44 through 49, where they define an immunotoxin conjugate as including a cell-surface binding ligand comprised of an antibody or fragment thereof. Thorpe et al. do not teach or even suggest the CD30 ligand polypeptides set forth in the present claims.

The basis of the rejection appears to be substitution of the present CD30L polypeptides for the anti-CD30 antibodies of Thorpe et al., apparently on the suggestion of Verheul et al. to use natural ligands (or fragments thereof) for the Interleukin-2 (IL-2) receptor, which receptor is (unlike the CD30 antigen) composed of two different chains

(or subunits). However, Verheul et al. do not disclose (or even suggest) the existence of the CD30 protein, or that it might be desirable target in the way that the IL-2 receptor is, nor do Verheul et al. disclose or suggest the CD30L polypeptides recited in the present claims. Stein et al. do not cure these deficiencies. Applicants respectfully submit that there is neither a teaching nor a suggestion in the cited art to make the combination of references set forth by the Examiner. The suggested combination appears to be a result of the impermissible use of hindsight in using applicants' own teachings to find various elements of the claimed invention in the prior art and combine them in a manner similar to that disclosed and claimed in the present application.

Moreover, even if the prior art had provided some motivation to combine the references in the manner set forth by the Examiner without reference to the instant specification, applicants respectfully submit that the combination of references is not available under 35 USC § 103(a). In fact, the only references cited by the Examiner that teach or suggest CD30L polypeptides are Smith et al. and Goodwin et al., both of which disclose applicant's own work and neither of which were published more than one year prior to the filing date of the present application. Thus, if, for the sake of argument, the combination of prior art references set forth by the Examiner were considered to suggest the present invention, applicants are permitted under 37 CFR § 131 to establish that they had possession of the invention prior to the effective dates of the references.

Accordingly, applicants respectfully submit that they had possession of that which was disclosed by Smith et al. and/or Goodwin et al. prior to the effective (i.e., publication) dates thereof, and direct the Examiner's attention *to In re Stempel* (USPQ 77, 81, CCPA 1957), which was cited in the previous response (a copy is included herewith for the Examiner's convenience as Exhibit A). According to the court in *In re Stempel*, "In the case of a reference, it is fundamental that it is valid for what it discloses and if the applicant establishes priority with respect to that disclosure, and there is no statutory bar, it is of no effect at all." *In re Stempel*, 113, USPQ 77, 81 (CCPA 1957). The court further held that "under the law all the applicant can be required to show is priority with respect to so much of the claimed invention as the references happens to show." (*Id.*).

Applicants are submitting herewith a Declaration (partially executed) of the inventors of the instant invention, (three of whom are co-inventors on the Goodwin et al. publication, and all of whom are co-authors of the Smith et al. paper) under 37 CFR § 1.131 demonstrating that they had possession of the subject matter disclosed in Smith et

al. and Goodwin et al. (namely, CD30L polypeptides) prior to the publication thereof. Moreover, applicants respectfully point out that neither Smith et al. nor Goodwin et al. have an effective date more than one year prior to the filing date of the present application. Accordingly, applicants have demonstrated priority with respect to the disclosure of Smith et al. and Goodwin et al., and the subject matter that the Examiner has cited from Smith et al. and Goodwin et al. is not prior art to the instant invention. The rejection thus rests on Thorpe et al. in view of Verheul et al., and Stein et al., none of which disclose or suggest the presently claimed invention or the CD30L polypeptides recited in the claims. Applicants respectfully request that the rejection under U.S.C. § 103(a) be withdrawn.

With respect to the ownership of the subject matter of the various claims currently pending in this application, applicants affirm that the subject matter and the claimed invention were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person or entity.

CONCLUSIONS

Claims 27-30, 32-46 and 50-69 are now pending in the application and are believed to be in condition for allowance. If the examiner has any questions or concerns about the present claims, she is asked to contact the undersigned at the direct dial number given below, to facilitate prosecution and speed allowance of the claims.

Respectfully submitted,

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